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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/843,051 | 04/26/2001 | Martin T. Gerber | P-8436.03CIP1 | 8909 |

27581 7590 10/19/2004

MEDTRONIC, INC.
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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT PAPER NUMBER

3762

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/843,051 | Applicant(s) GERBER ET AL. | |
| | Examiner George R Evanisko | Art Unit 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8-13 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 16-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed 2/20/03.

Newly submitted claim 21 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The inventions are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process.

(MPEP § 806.05(e)). In this case the process as claimed can be practiced by another materially different apparatus not requiring an electrode connector coupled to the coil electrode and the conductor connected to the connector but a lead using no electrode connector and the conductor connected directly to the electrode. In addition, the apparatus as claimed can be used to practice another and materially different process not requiring stimulating the nerve but sensing of the nerve.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 21 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 8, and 10-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Schaer (6251107). Schaer provides a flexible coil electrode that can be intravascularly positioned and is therefore capable of meeting the functional use recitations presented in the claims. In addition, element 34 is considered to be the electrode connector since it is both coupled/connected/adhered to the coil electrode and conductor. Also, any of the other coil electrodes can be considered to be the claimed “ring shaped electrode” located proximal or distal to a coil electrode. Finally, for claims 8 and 10, Schaer shows in figure 3 the connector having “substantially” common outer diameters.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, and 11-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Speicher et al (4603705). Speicher is capable of meeting the functional use recitations presented in the claims since he use an implantable, flexible coil electrode. In addition, Speicher meets the claimed limitation of "about 2 mm" since his coil diameter is "about 3 mm" (col 5). Also, Speicher shows the electrode connectors (20, 22, 50, or 52) connected to one another in connection zones or adhered to (dictionary definition of adhered of "to give support" or "to hold fast or stick by") since the coil electrode and connector are maintained in connection with each other to provide the implantable lead. Finally, Speicher show the ring shaped electrode as the other coiled electrode or conductive electrode connectors 20, 22, 50, or 52.

In the alternative, Speicher discloses the claimed invention except for the coil diameter being from about 0.5 mm to about 2.0 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead with coil electrode as taught by Speicher, with a coiled electrode having a diameter of about 0.5 mm to about 2.0 mm since it was known in the art that implantable leads with coil electrodes use a coil electrode of about 0.5 mm to about 2.0 mm to provide an implantable lead having a coil electrode that is small and unobtrusive. In addition, one skilled in the art would have expected

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both the applicants claimed invention and Speicher's invention to have the same properties even though the ranges do not overlap since both are used for providing an implantable lead with flexible coiled electrodes. (According to MPEP 2144.05, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties).

Claims 3 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speicher et al.

Speicher discloses the claimed invention except for the electrode connector and coil electrode being butt-welded together and the coil electrode and electrode connector having substantially common inner diameters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead with coil electrode as taught by Speicher, with the electrode and connector being butt-welded together since it was known in the art that implantable leads use a butt-weld to connect electrodes and connectors to provide a secure and easily produced connection to connect the two elements together.

In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the implantable lead as taught by Speicher with the electrode connector and coil electrode being butt-welded together and the coil electrode and electrode connector having substantially common inner diameters, because Applicant has not disclosed that the electrode connector and coil electrode being butt-welded together and the coil electrode and electrode connector having substantially common inner diameters provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art,

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furthermore, would have expected Applicant's invention to perform equally well with the electrode connector and coil electrode being connected together and the inner diameters not being substantially the same as taught by Speicher, because Speicher provides a coil electrode and connector that is flexible and implantable.

Therefore, it would have been an obvious matter of design choice to modify Speicher to obtain the invention as specified in the claim(s).

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612.

The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


George R Evanisko
Primary Examiner
Art Unit 3762

10/17/04

GRE
October 17, 2004